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.10/633,306	08/04/2003	Arthur L. Castle	GENE-106/02US	3420	
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COOLEY GODWARD KRONISH LLP			MILLER, MARINA I		
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/633,306	CASTLE ET AL.			
Office Action Summary	Examiner	Art Unit			
	Marina Miller	1631			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	I. lely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 29 Se	eptember 2006.				
	action is non-final.				
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	i3 O.G. 213.			
Disposition of Claims		·			
4)⊠ Claim(s) <u>1-17 and 20-22</u> is/are pending in the application.					
4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1-17 and 20-22</u> is/are rejected.					
7) Claim(s) is/are objected to.		•			
. 8) Claim(s) are subject to restriction and/or	election requirement.				
Application Papers					
9) The specification is objected to by the Examiner	r.				
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.					
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correcti	on is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).			
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some ★ c) None of:					
 Certified copies of the priority documents have been received. 					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the prior	· ·	ed in this National Stage			
application from the International Bureau	• • • • • • • • • • • • • • • • • • • •				
* See the attached detailed Office action for a list of the control of the contro	of the certified copies not receive	d.			
Attachment(s)	A) []]	(DTO 442)			
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da				
3) Information Disclosure Statement(s) (PTO/SB/08) 5) Notice of Informal Patent Application					
Paper No(s)/Mail Date	6)				

Applicants' submission filed on 9/29/2006 is acknowledged.

Claims 1-22 are pending.

Claims 18-19 are withdrawn again from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claims. Election was made with traverse in the response filed 1/19/2006.

Claims 1-17 and 20-22 presently are under examination.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

Claims 1-17 were rejected under 35 U.S.C. 101 in the office action mailed 3/29/2006 because the claims were directed to non-statutory subject matter. Applicants amended the claims and argue that the amended claims recite an active step of performing at least one hybridization assay. In light of applicants' arguments on page 8 of the response filed 9/29/2006, the amended claims are interpreted to recite an active step of performing at least one hybridization assay, and the rejection is hereby withdrawn.

Claim Rejections - 35 USC § 112

First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is NEW MATTER rejection.

Claim 1, as amended, recites obtaining gene expression data by *at least one* hybridization assay. However, a method wherein more than one hybridization assay is performed does not have support in the specification, claims, or drawings, as originally filed. Applicants pointed to paragraph [0078] of the specification for support. The specification, and specifically paragraphs [0078]-[0094], teaches various hybridization assay *formats* for collecting gene expression information (*e.g.*, Northern blot, Southern blot, dot blot, solution-based assay, PCR, PT-PCR, etc.), but does not disclose that more than one assay (*e.g.*, two simultaneously/sequentially conducted dot blots or PCR and a dot blot) is used for collecting data in the instant invention. For these reasons, the claims are rejected for reciting new matter.

Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentations is "undue." These factors include, but are not limited to:

- a) The breadth of the claims;
- b) The nature of the invention;
- c) The state of the prior art;
- d) The level of one of ordinary skill;
- e) The level of predictability in the art;
- f) The amount of direction provided by the inventor;
- g) The existing of working examples; and
- h) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. 858 F.2d at 740. While all of these factors are considered, sufficient amount for a prima facie case are discussed below.

Claims 1-17 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

a) Claim 1 is broad because it is drawn to a method for identifying an unknown marker using a test and control sample which are not distinguished/identified and analyzing gene expression, without a step of comparing test and control expression levels and/or looking only at

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one gene/marker to identify a tissue/cell. Therefore, claim 1 is not enabled.

It is noted that claims 2-8 and 17 do recite a difference between a test and control sample (exposed to a toxin and administering a drug). However, claim 1 limits the method to specifically EXCLUDE particular variables; one of the variables recited for exclusion is a magnitude of difference in expression between a test and control sample, and the other is behavior of other genes. If claims 2-8 and 17 specifically exclude comparing test and control expression levels, even if behavior of multiple (i.e. "other") genes is included, claims 2-8 and 17 are still not enabled because neither the prior art nor the instant specification teach how to identify markers without comparing expression in test and control samples.

Also, the claims specifically recite identifying marker genes in tissue. In this case, multiple markers need to be identified (see Xiong, *Mol. Genet. and Metabolism*, 73:239-247 (6/27/2001) cited below) because most genes individually do not offer good predictive ability in tissue. Thus, the instant claims are not enabled for identifying markers in tissue where analysis of "other" genes is excluded because more than one marker is required for tissue analysis.

Without knowing what marker is identified OR for what effect/tissue/disease the marker is identified, the identification of a marker would require undue experimentation. Further, without comparing a test and control sample for determining whether expression levels of genes change in a test sample as compared to a control, the identification of a marker would also require undue experimentation. Also, without identifying a *set* of genes/markers for tissue, the identification of a marker for a tissue would require undue experimentation.

b) The invention is drawn to a method for identifying a marker gene for predicting a biological response in cells or tissue.

c), e) Prior art discloses identifying marker genes for tumor and normal tissue and using the Fisher linear discriminant function, wherein gene expression levels of tumor and normal tissues are taken into account and **multiple** marker genes are identified for a tumor classification. *See* Xiong, *Mol. Genet. and Metabolism*, 73:239-247 (6/27/2001). In fact, Xiong discloses that "most genes individually do not offer good predictive ability." *Id.*, at 242. Xiong further discloses optimal sets of genes for tumor classification. *Id.*, at 243. The instant claims do not recite what marker and/or for what result/tissue a marker is identified, analyzing changes in gene expression with regard to a control sample, and identifying tissue by looking at only one gene/marker.

- d) The skill of those in the art of molecular biology and bioinformatics is high.
- f) The specification does not provide any working examples and does not teach how to make and use a method of identifying markers in cells or tissue without knowing for what tissue/result a marker is identified; and/or without comparing test and control gene expression levels, and/or without multiple marker genes for identifying tissue.
- h) In order to practice the claimed invention, one skilled in the art must randomly select a control sample, tissue, and/or disease and must guess what test gene expression levels correspond to a disease or tissue. This constitutes undue experimentation.

Due to the undue experimentation required to obtain the goal of the invention, the lack of directions presented in the specification, the complex nature of the invention, and the state of the prior art showing identifying marker genes for known difference between a test and control sample, taking into account test and control gene expression levels, and using multiple marker genes for tissue analysis, the specification fails to teach one skilled in the art how to use the

claimed method for identifying marker genes.

Second Paragraph

Claims 1-17 and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

New Rejections

Claim 3 recite the limitation "wherein step (b) does not rely on a correlation matrix to account for relationships or interdependencies between the genes." It is not clear what "correlation" (e.g., between genes, probabilities, expression levels, cells, etc.) is intended to be reflected in "a correlation matrix."

Further, the limitation "to account for" makes the claim vague and indefinite because it is not clear what specific steps or criteria of "accounting" are intended.

It is also unclear whether "accounting" is intended to be an active, positive method step of merely an intended use of the method.

It is further unclear whether step (b) of claim 3 does not included a factor selected from a group of: the magnitude of the difference and the behaviors, AND does not rely on a correlation matrix; OR only does not rely on a correlation matrix.

As the intended limitation is not clear, claim 3 is indefinite.

Claim 4 recites "claim 2, wherein step (b) comprises computing probability." Claim 4 depends from claims 1 and 2. It is not clear where "computing probability" fits within step (b) of

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claims 1 and 2, and whether step (b) recited in claim 4 is intended to substitute step (b) of claims 1 and 2. As the intended limitation is not clear, claim 4 is indefinite.

Claim 9 recites "claim 1, wherein step (b) comprises determining a scoring function and a discriminate score." It is not clear where "determining a scoring function and a discriminate score" fits within step (b) of claim 1, and whether step (b) recited in claim 9 is intended to substitute step (b) of claim 1. As the intended limitation is not clear, claims 9-12 are indefinite.

Answer to Arguments

Claim 1 recites the limitation "to identify ... marker genes" and "thereby identifying." The claim was rejected in the previous office action because it was not clear whether "to identify" and "thereby identifying" were intended to be active, positive steps or merely an intended result of the method. Applicants argue that the limitations (*i.e.*, to identify and thereby identifying) does recite active positive steps of "obtaining gene expression data," "analyzing the expression data," and "predicting a toxic response" (p. 9 of the response).

In response, it is noted that the claimed method does not recite an active, positive step of "identifying marker genes" and "predicting a toxic response." The instant method only comprises steps of obtaining expression data and analyzing the data. Further, from applicants' arguments, it is not clear whether the method is intended to comprise steps of obtaining, analyzing, and predicting a toxic response; steps of obtaining, analyzing, and identifying; OR steps of obtaining, analyzing, and identifying, wherein the step of identifying is further intended to comprise another obtaining and analyzing step and also a step of predicting a toxic response. The examiner maintains that it is not clear whether "to identify" and "thereby identifying" is

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intended to be an active, positive method step and that the relationship of the method steps and the preamble is unclear, and therefore the rejection of claims 1-17 is also maintained.

New claims 20-22 depend from claim 1, and therefore are also indefinite.

Claim 10 recites a parameter z_i in the formula. However, neither the claims nor the specification defines the parameter. Applicants did not address the rejection. The examiner maintains that the limitation is indefinite, and therefore the rejection of claims 10-12 is also maintained.

Claim 10 recites "the discriminate score for sample Z." The claim was rejected because it was not clear whether "the discriminate score for sample Z" was intended to be "the discriminate score for each gene" recited in claim 9 or a different discriminate score (e.g., for a sample).

Applicants argue that because claim 10 comprises all limitations of claim 9, "the discriminate score for sample Z" IS "the discriminate score for each gene." In response to the argument, it is noted that the relationship of "the discriminate score for sample Z" recited in claim 10 and "a discriminate score for each gene" recited in claim 9 is still not clear. Specifically, it is not clear whether claim 10 recites, for example, the discriminate score for each gene IN sample Z, a cumulative discriminate score for all genes in sample Z, an average of the gene discriminate scores in sample Z, etc. Therefore, the examiner maintains that the limitation is still indefinite, and therefore also maintains the rejection of claims 10-12.

Claim 10 recites "the variance" in lines 10 and 12. The claim was rejected previously

because there is insufficient antecedent basis for this limitation in the claim, *i.e.*, neither claim 1 nor claim 9 from which claim 10 depends recites a variance in the distribution of gene expression. Applicants argue that because claim 9 recites a scoring function and claim 10 recites a specific scoring function comprising "variances," the limitation "variances" has antecedent basis in claim 9. In response, it is noted that although claim 9 recites "a scoring function," claim 9 does not recite a "variance" of a specific scoring function recited in claim 10. Therefore, the examiner maintains that there is insufficient antecedent basis for the limitation "the variance" in claim 10, and therefore the rejection of claims 10-12 is also maintained.

Claim 11 recites the limitation "a discriminate score for each gene." Claim 11 depends from claims 1, 9, and 10, wherein claim 9 recites "a discriminate score for each gene." Claim 11 was previously rejected because it was not clear whether "a discriminate score for each gene" recited in claim 11 is intended to be the same or different from "a discriminate score for each gene" recited in claim 9. Applicants argue that claim 9 and 11 recite the same "discriminate score for each gene." In response, it is noted that the antecedent basis of the limitation recited in claim 11 is still not clear because claims 9 and 11 both recite "a discriminate score for each gene." The examiner maintains that claims 11-12 are indefinite, and therefore the rejection is also maintained. This rejection may be overcome by replacing "a" with --the-- before "discriminate" in claim 11.

Claim 12 recited "the discriminate score for each gene." Claim 12 depends from claims 1, 9, 10, and 11. Claim 12 was previously rejected because claims 9 and 11 both recite the

limitation "a discriminate score for each gene" which may or may not be the same (see above) and the antecedent basis of the limitation recited in claim 12 was not clear. Applicants argue that claim 9 and 11 recite the same "discriminate score for each gene." In response, it is noted that the antecedent basis of the limitation recited in claim 11 is still not clear because claims 9 and 11 both recite "a discriminate score for each gene." The examiner maintains that claims 11-12 are indefinite, and therefore the rejection is also maintained. Applicant is advised that amending claim 11 as recommended above will overcome both the rejection of claim 11 and this rejection.

Claim 12 recites the parameters Xi; Yj; i=1...t; j=1...n. The claim was previously rejected because the parameters were not expressly defined either in the claims or in the specification. Applicants directed the examiner to page 12 of the specification for the definitions of the parameters. However, after reviewing page 12, it is still not clear whether Xi is an expression level of i-th gene or an i-th expression level for a gene X (e.g., multiple measurements for a gene). Accordingly, it is not clear whether "i" is a number of genes or a number of measurements for a gene. Also, parameters Yj and "j" are indefinite for the same reasons. The examiner maintains that claim 12 is indefinite, and therefore the rejection is also maintained.

Claim Rejections - 35 USC § 102

Claims 1-5, 9-14, and 16-17 were previously rejected under 35 U.S.C. 102(e) as being anticipated by Mendrick, WO 02/10453. Applicants argue that WO 02/10453 is not a prior art under 35 U.S.C. 102(e) and submitted Exhibit A as a proof that the international filing date of

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corresponding application PCT/US01/23872 is 7/31/2001 and that the international filing date printed on the published PCT application (*i.e.*, 7/30/2001) is a typographical error. In light of the submission, the rejection under 35 U.S.C. 102(e) over Mendrick, WO 02/10453 is withdrawn.

Claim Rejections - 35 USC § 103

Claims 1-3, 6-7, 9, 13-17, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golub, *Science*, 286:531-537 (15 Oct. 1999), in view of Lindon, *Progress in Nuclear Magnetic Res. Spectroscopy*, 39:1-40 (2001), and further in view of Xiong, *Mol. Genet. and Metabolism*, 73:239-247 (6/27/2001).

Rejection of new claims 20-22.

Golub discloses a method for identifying marker genes for classifying cancer (abstract). Golub discloses obtaining gene expression data for variety of samples using hybridization (*i.e.*, test and control) (see p. 531, two last full paragraphs; p. 53, notes 13 and 23). Golub discloses analyzing the gene expression data to identify marker genes by a "neighborhood analysis" method (p. 532). Golub discloses identifying marker genes for acute lymphoblastic leukemia and acute myeloid leukemia (532). Golub also discloses an array comprising at least hundred probes. It is noted that Golub specifically teaches use of multiple genes and comparison of test vs. control samples.

Golub does not disclose using a linear discriminate metric that does not include the magnitude of the difference in gene expression.

Lindon discloses application of a well-known pattern recognition method such as linear discriminant analysis (LDA) (p. 16-17), wherein a linear discriminate metric does not depend

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from the relative magnitude of response (p. 17). Lindon also discloses differential gene expression as a result of disease or toxicity (e.g., effect of a drug) (p. 3). Lindon discloses measuring mRNA (p. 3).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Golub to use the analysis of Lindon, specifically, LDA, such as taught by Lindon, where the motivation would have been to use a pattern recognition method that performs better than other statistical methods and provides a practical and accurate method for analysis using gene expression, as taught by Xiong, p. 247.

Answer to arguments regarding claims 1-3, 6-7, 9, and 13-17.

The instant claims were previously rejected over Golub, Lindon, and Xiong. Applicants argue that Lindon does not teach a linear discriminant analysis (LDA) to analyze gene expression, but instead teaches analysis of small molecule metabolites in biofluids with NMR (page 11 of the response). Applicants further argue that Lindon teaches away from the instant invention because Lindon favors other studies over gene expression studies. Applicants also argue that there is no reasonable expectation of success in combining the references because Lindon "calls into question the use of gene expression analysis" (page 11 of the response).

In response to the argument that Lindon teaches away from the instant invention, it is noted that Lindon discloses well-known pattern recognition methods and their application in biomedical science (specifically NMR). Lindon further discloses a concept of genomics based on "gene chips" and statistical processing/classification of gene expression data using well-known statistical methods (e.g., LDA) (p. 3, 7-8; fig. 4-50). Lindon does not teach away from analyzing

gene expression data, but only discloses that proteomics may be used to answer questions wherein genomics may only provide a semi-quantitative approach (*e.g.*, wherein analyzed DNA is non-coding) (p. 3-4). Lindon also discloses that one may use a combination of genomics and proteomics for predicting disease progression, drug therapeutic effects or drug toxicity (p. 4). Lindon discloses various statistical methods for identification and interpretation of a non-random behavior in a complex system and application of the statistical methods in various areas, *e.g.*, chemistry, psychology, fingerprinting, and linguistics (p. 7). Lindon illustrates the application of the well-known statistical methods **including LDA** to a classification of a sample based on measurements in the specific context of NMR (p. 8, left col; p. 16-17). Thus, the examiner maintains that Lindon does not teach away from the instant invention, and does teach use of LDA.

Applicants are reminded that the rejection is made under 35 U.S.C. 103(a) over a combination of references wherein Xiong also discloses applying LDA (Fisher LDA) to a gene-expression based classification of tumors (p239-240).

To further answer the arguments, one of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings of Golub, Lindon, and Xiong because pattern recognition algorithms are widely used for the identification of behavior in a complex chemical and biological systems, as taught by Lindon (p. 7), and for classifying tumor and normal tissues using gene expression analysis, as taught by Xiong, p. 240. For these reasons and those previously set forth, the rejection is maintained.

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Claims 4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golub, *Science*, 286:531-537 (15 Oct. 1999), in view of Lindon, *Progress in Nuclear Magnetic Res. Spectroscopy*, 39:1-40 (2001), and further in view of Xiong, *Mol. Genet. and Metabolism*, 73:239-247 (6/27/2001), as applied to claims 1-3, 6-7, 9, and 14-17, and further in view of James, Functional Linear Discriminant Analysis for Irregularly Samples Curves, *J. of the Royal Statistical Society Series*, B 63:533-550 (Feb. 13, 2001).

Claims 4 and 8 were previously rejected over Golub, Lindon, Xiong, and James.

Applicants did not specifically address the rejection over the combination of references. The examiner maintains that Golub, Lindon, Xiong, and James make claims 4 and 8 obvious, and therefore also maintains the instant rejection.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Golub, *Science*, 286:531-537 (15 Oct. 1999), in view of Lindon, *Progress in Nuclear Magnetic Res.*Spectroscopy, 39:1-40 (2001), and further in view of Xiong, *Mol. Genet. and Metabolism*, 73:239-247 (6/27/2001), as applied to claims 1-3, 6-7, 9, and 14-17, and further in view of MacGregor, *Toxicological Science*, 59:17-36 (2001).

Claim 5 was previously rejected over Golub, Lindon, Xiong, and MacGregor. Applicants did not specifically address the rejection over the combination of references. The examiner maintains that Golub, Lindon, Xiong, and MacGregor make claim 5 obvious, and therefore also maintains the instant rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-6, M-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, Ph. D. can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Marina Miller Examiner Art Unit 1631

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